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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,364	07/05/2001	Paul D. van Poelje	MET-037CXT	7049

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
10/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/900,364	VAN POELJE ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 115-179* is/are pending in the application.

4a) Of the above claim(s) *123,125,127,128,141-144 and 147-179* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,115-122,124,126,129-140,145 and 146* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/06, 8/31/06, 7/24/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Election/Restrictions

In the response to the election of species requirement received 4/24/2006 the applicant's elected sulfonylurea antidiabetic agents with the specific specie being glyburide, and a FBPase inhibitor of Formula I with the specific specie being compound J. There was no traversal of the election of species requirement and thus it is made final.

Response to Amendment

The applicant's amendment received 05/31/2007 amending claims 115, 119, 148 and 152 to correct the functional groups claimed therein. The examiner respectfully points out that the applicant's did not specifically point to where in the specification support was provided for such changes, nor did applicant's state that no new matter was created by the amendments. The examiner however has considered the amendments and has entered them.

Claims 1, 115-122, 124, 126, 129-140, 145 and 146 are pending.

Claims 123, 125, 127, 128, 141-144 and 147-179 have been withdrawn from consideration as being drawn to a non-elected invention.

Claims 2-114 are canceled.

Response to Arguments

Applicant's arguments filed 05/31/2007 have been fully considered but they are not persuasive. The applicant's have argued the obviousness double patenting rejection as failing to parralel the guidelines for a 103(a) rejection. The examiner respectfully points out that while the rationale and logic of the ODP does parallel that of the 103(a) rejection there is no requirement for it to be written or formatted exactly as such. In the present case the applicant's are arguing that the examiner pointing out that the '033 patent has in its issued claims open claim language encompassing the presently written claims is insufficient to achieve obviousness. The examiner disagrees. The open claim language of the '033 patent as set forth in the ODP rejection of the last office action clearly encompasses the inclusion of a "at least one insulin secretagogue and a FBPase inhibitor". There is no limitation as to any additional agents being included. Thus the currently claimed invention is *prima facie* obvious.

the applicants argue on pages 31-32 that the 103(a) rejections are improper as the combination of glyburide with the claimed FBPase inhibitors demonstrates unexpectedly superior results. The examiner respectfully points out that the data in examples (example Y, etc..) is written in the present tense and thus indicates that the examples are prophetic. As such the examples cannot provide evidence of unexpectedly superior results.

For the reasons above and for the reasons of record the obviousness double patenting rejections and the 103(a) rejections are maintained. The amendments made

by the claims do not change the scope or breadth of the claims and as such are encompassed by the rejections of record accordingly. the rejections are included below. **This action is made final.**

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 115-122, 124, 126, 129-140 and 145-146 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51-55 of U.S. Patent No. 6965033. Although the conflicting claims are not identical, they are not patentably distinct from each other because current claim 1 is drawn to a pharmaceutical composition comprising at least one insulin secretagogue and a FBPase inhibitor selected from the group of formula I or IA, and '033 claim 51 is drawn to a method of treating diabetes comprising administering a compound of formula I

(wherein formula I is equivalent to the compunds of currently claimed formula I and IA). As the '033 patent uses the open language "comprising" additional antidiabetic compounds can be administered including sufonylureas such as glyburide.

Claims 1, 115-122, 124, 126, 129-140 and 145-146 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6756360. Although the conflicting claims are not identical, they are not patentably distinct from each other because current claim 1 is drawn to a pharmaceutical composition comprising at least one insulin secretagogue and a FBPase inhibitor selected from the group of formula I or IA, and '360 claim 1 is drawn to a pharmaceutical composition comprising an insulin sensitizer agent and an FBPase inhibitor. In '360 claim 4 the FBPase inhibitor is a compound selected from the formula I and IA wherein formula I and IA are identical to the formula I and IA of the current claim 1. Further glyburide is a known insulin sensitizer and secretagogue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 115-122, 124, 126, 129-140 and 145-146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erion et al. (US Patent No. 6756360) in view of Weber et al. (US Patent No. 3454635).

The applied reference has a common assignee and inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37

CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Erion et al. teach, in the abstract, pharmaceutical compositions containing an FBPase inhibitor and an insulin sensitizer, as well as methods for treating diabetes and diseases responding to increased glycemic control, improved insulin sensitivity, a reduction in insulin levels, or an enhancement of insulin secretion. In col. 4 lines 45-50, Erion et al. teach that an aspect of the invention is to use FBPase inhibitors in combination with insulin sensitizer therapies that include administration of agents that enhance endogenous or exogenous insulin levels, such as sulfonylureas, insulin, or insulin mimetics. In col. 190 lines 1-20, Erion et al. teach a particular FBPase inhibitor used in their biological assays called Compound J. The Compound J detailed in the '630 patent is identical to the currently claimed compound J.

Erion et al. does not teach the use of Compound J with the particular sulfonylurea antidiabetic glyburide.

Weber et al. teach, in col. 1 line 20 to col. 2 line 5, benzenesulfonyl ureas having hypoglycemic activity of the formula detailed in lines 22-28. In col. 5 lines 5-75, Weber et al. teach compound IV (glyburide) as having strong hypoglycemic action when administered orally. The compound can be used in the manufacture of orally

administrable pharmaceutical preparations for the lowering of blood sugar in the treatment of diabetes mellitus and can be used in their pharmaceutically acceptable salt forms. The compositions can be in the forms of tablets with a suitable pharmaceutically acceptable carrier and can be given in dosage per unit amounts to 0.5-100mg but higher and lower dosages can be utilized.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use glyburide in combination with a FBPase inhibitor, as Erion teaches such a combination. Further Erion et al. disclose Compound J as an FBPase inhibitor in the '630 patent and this compound is the same Compound J as currently claimed. Compound J is taught as useful in the treatment of diabetes and glyburide is a known antidiabetic agent.

The examiner respectfully points out the following from MPEP 2144.06:
"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Claims 1, 115-122, 124, 126, 129-140 and 145-146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al. (US Patent No. 6965033) in view of Weber et al. (US Patent No. 3454635).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Jiang et al. teach, in the abstract, novel bisamidate phosphonate prodrugs of FBPase inhibitors of formula IA and their use in the treatment of diabetes and other conditions associated with elevated blood glucose. Jiang et al. teach, in col. 29 line 5 to col. 31 line 55, compounds of formula i, wherein R^{55} can be moiety 1 of group1; A can be NH_2 (moiety 1); B can be –iBu (moiety 2); Q^1 and Q^2 can both be moiety 2; and R^{14} can be OEt. This gives Compound J of the currently claimed application.

Jiang et al. does not teach the use of the FBPase inhibitor specified above in conjunction with the antidiabetic sulfonylurea glyburide.

Weber et al. teach, in col. 1 line 20 to col. 2 line 5, benzenesulfonyl ureas having hypoglycemic activity of the formula detailed in lines 22-28. In col. 5 lines 5-75, Weber et al. teach compound IV (glyburide) as having strong hypoglycemic action when administered orally. The compound can be used in the manufacture of orally administrable pharmaceutical preparations for the lowering of blood sugar in the treatment of diabetes mellitus and can be used in their pharmaceutically acceptable salt forms. The compositions can be in the forms of tablets with a suitable pharmaceutically acceptable carrier and can be given in dosage per unit amounts to 0.5-100mg but higher and lower dosages can be utilized.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use glyburide in combination with a FBPase inhibitor, as Jiang et al. teach that FBPase inhibitors are useful in the treatment of diabetes and Weber discloses that sulfonylureas are antidiabetic agents. Further Jiang et al. disclose a FBPase inhibitor identical to currently claimed Compound J. Compound J is taught as useful in the treatment of diabetes and glyburide is a known antidiabetic agent.

The examiner respectfully points out the following from MPEP 2144.06:
"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER